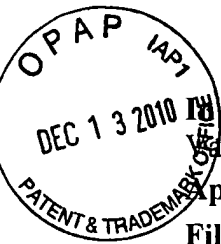


*DM*



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Inventor application of:** Jacques Thilly and Christian Vandecasserie

**Application No.** 10/524,886

**Filed:** December 1, 2005

**Confirmation No.** 2976

**For:** CLOSURE SYSTEM FOR A VIAL, VIAL,  
METHOD OF CLOSING AND FILLING A  
VIAL AND A STAND FOR A VIAL

**Examiner:** James N. Smalley

**Art Unit:** 3781

**Attorney Reference No.** 8121-82019-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

Attorney or Agent  
for Applicant(s)

*[Signature]*

Date Mailed December 7, 2010

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

INTERVIEW SUMMARY

Applicants appreciate the Examiner's courtesy in holding an interview concerning this case with the undersigned on October 18, 2010, and the further brief discussions of the case on November 2 and November 15.

On October 18, 2010, Applicants and the Examiner discussed whether the addition of "snap fit connection" language in claims 1, 10, and 11, would cause the claims to be allowable as Applicants argued that the applied publications do not disclose or suggest a snap-fit connection. The Examiner was optimistic regarding this proposal, but suggested that more structural language might be preferable and that the Office would need to consider the issue. No agreement was reached.

On November 2, 2010, the Examiner contacted the undersigned to express that the Office had some concerns with regard to whether the previously discussed addition of the "snap fit connection" language includes sufficient structure. The Examiner suggested that Applicants amend the claims to claim the feature with further structure. No agreement was reached at that point. However, after that discussion, Applicants proposed an amendment by email on November 11 to add to claims 1, 10, and 11, the feature (generally) that the snap-fit part is

resiliently deformable so that it may deform to fit over the rim of the vial and then resiliently snap back to engage the flange of the vial via a snap-fit connection.

On November 15, 2010, the Examiner and the undersigned discussed the Office's further preference that the language concerning the deformation of the snap fit parts be recited more positively. No agreement was reached. Applicants proposed an Examiner's Amendment by email on November 22, 2010, more positively reciting the deformability of the snap fit part. Agreement that the Office would allow the case as so amended was reached through email correspondence thereafter.


Applicants' proposed amendments of October 18 and November 11 and 22 and further email correspondence regarding the proposed Examiner's Amendment are attached hereto.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

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By

  
Kevin M. Hayes  
Registration No. 54,158

## Emmy Burns

---

**From:** Kevin M. Hayes  
**Sent:** Monday, October 18, 2010 10:10 AM  
**To:** 'james.smalley@uspto.gov'  
**Cc:** Emmy Burns  
**Subject:** App. No. 10/524,886 by Thilly & Vandecasserie  
**Attachments:** Listing of Claims for discussion.doc

Dear Examiner Smalley:

Thank you for agreeing to discuss this case with us today at 3 p.m. ET (12 PT). Attached is a potential mark-up of the claims for discussion, which includes a potential amendment that was suggested in your Office action of June 9, 2010, on page 2.

Best regards, Kevin  
Kevin Hayes  
Klarquist Sparkman, LLP  
One World Trade Center  
121 S.W. Salmon Street, Suite 1600  
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### **Listing of Claims for Discussion**

1. (Potential amendment) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial, and wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity able to engage with the clamp part via a snap-fit connection.

2. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 1 wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the sealing ridge being detachable from the clamp part.

3. (Cancelled)

4. (Previously presented) A closure system according to claim 1 wherein said frangible link is linked to the skirt wall of the cover part.

5. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 1 further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

6. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 5 wherein the clamp part comprises:

an upper wall having the aperture therein, from which the peripheral skirt wall extends downwardly, and

wherein said upper wall and the upwardly convex part of the closure part are profiled such that the upwardly convex part bulges above the adjacent upper surface of the upper wall.

7. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 6 wherein said upper surface of the clamp part and the upwardly convex part of the closure part are profiled to form a smooth convex shape.

8. (Previously presented) A closure system according to claim 1 wherein the upper surface of the closure part adjacent to the said region is made of a thermoplastic elastomer material.

9. (Previously presented) A closure system according to claim 1 characterized in that the clamp part is made of a moldable plastics material and is engageable with the rim bounding the mouth opening of the vial.

10. (Potential amendment) A pharmaceutical vial having an upwardly facing mouth opening closed /by a closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial, and wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity able to engage with the clamp part via a snap-fit connection.

11. (Potential amendment) A method of closing a vial having an upwardly-facing mouth opening bounded by a rim in the form of a flange having upper and lower surfaces extending transverse to its upper-lower axis, comprising

inserting into the mouth opening an elastomer closure part shaped to sealingly engage with the mouth opening, and having a lower surface to face the interior of the vial and an opposite upper surface to face away from the vial, and capable of being punctured by a needle,

providing a clamp part able to engage with the flange around the rim of the mouth opening of the vial by a resilient snap-fit engagement of a snap fit part of the clamp part underneath a downwardly facing surface of such a flange part, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the

mouth opening, wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial, engaging the clamp part with the assembly of vial and closure part by said snap-fit engagement,

providing a cover part comprising an upper wall and a peripheral skirt wall, said cover part being engageable with the clamp part by means of a snap-fit between the clamp part and the skirt wall, wherein when so engaged said cover part covers the closure part and a lower surface of the cover part faces the upper surface of the closure part and

engaging the cover part with the clamp part by said snap-fit so that the cover part engages the clamp part by a snap-fit connection.

12. (Previously presented – indicated to be allowed) A method of filling a pharmaceutical vial having an upwardly-facing mouth opening, comprising the steps of:

providing an assembly of an empty vial having an elastomer closure part shaped to sealingly engage with the mouth opening and having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle, and a clamp part engaged with the vial, and bearing upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial;

inserting a filling needle downwardly through the region of the upper wall of the closure part;

injecting a liquid medicament through the filling needle into the vial;

withdrawing the needle to leave a residual puncture hole;

engaging a cover part with the clamp part to cover the said region of the closure part by means of a snap-fit between a peripheral skirt wall of the cover part and the clamp part.

13. (Previously presented - indicated to be allowed) A method according to claim 12 further comprising, prior to engaging the said cover part, directing a source of heat at the residual puncture hole in the upper surface of the closure part to melt the elastomer material in the immediate locality of the puncture, and to thereby seal the residual puncture hole.

14. (Cancelled)

15. (Cancelled)

16. (Cancelled).

17. (Previously presented) A pharmaceutical vial according to claim 10 retained in a stand, where said stand comprises:

a ring-shaped body having an inner perimeter adapted to engage with the base of the vial; and

an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein,

wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.

18. (Previously presented - indicated to be allowed) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,



a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part,

further wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the sealing ridge being detachable from the clamp part.

19. (Previously presented - indicated to be allowed) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part

comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part,

further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

20. (Previously presented - indicated to be allowed) A pharmaceutical vial retained in a ring stand comprising:

A pharmaceutical vial having an upwardly facing mouth opening closed by a closure system, wherein the closure system comprises an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle; a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial; and a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture; wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part;

wherein the pharmaceutical vial is retained in a stand, where said stand comprises a ring-shaped body having an inner perimeter adapted to engage with the base of the vial and an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein, wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.

## Emmy Burns

---

**From:** Kevin M. Hayes  
**Sent:** Thursday, November 11, 2010 3:05 PM  
**To:** 'james.smalley@uspto.gov'  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie  
**Attachments:** potential amendment.doc

Dear Examiner Smalley:

Thank you for calling us on November 2, 2010. We understand from our discussion that the PTO has some concerns with regard to whether the previously discussed addition of the "snap fit connection" language includes sufficient structure. As we discussed on the 2<sup>nd</sup>, we understand that the PTO would agree that sufficient structure would be provided and the case should be allowed if Applicants amended the claims to include a further structural description of the snap fit connection. In that regard, we discussed an indication that the parts were resiliently deformable so that they could deform over the vial rim and snap back into place. We've attached a potential amendment making these changes. Please let us know if this would be acceptable. (You will see that we also propose to make a clarifying amendment in claim 11 to match the singular v. plural nature of the claim language.)

Best regards, Kevin  
Kevin Hayes  
Klarquist Sparkman, LLP  
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Portland, Oregon 97204  
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Facsimile: (503) 228-9446; (503) 595-5301

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**From:** Kevin M. Hayes  
**Sent:** Monday, October 18, 2010 10:10 AM  
**To:** 'james.smalley@uspto.gov'  
**Cc:** Emmy Burns  
**Subject:** App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley:

Thank you for agreeing to discuss this case with us today at 3 p.m. ET (12 PT). Attached is a potential mark-up of the claims for discussion, which includes a potential amendment that was suggested in your Office action of June 9, 2010, on page 2.

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### **Listing of Claims for Discussion**

1. (Potential amendment) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial, and wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial via a snap-fit connection, wherein the snap-fit engagement parts are resiliently deformable so that they may deform to fit over the rim of the vial and then resiliently snap back to engage the vial via a snap-fit connection,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

2. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 1 wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the

sealing ridge being detachable from the clamp part.

3. (Cancelled)

4. (Previously presented) A closure system according to claim 1 wherein said frangible link is linked to the skirt wall of the cover part.

5. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 1 further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

6. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 5 wherein the clamp part comprises:

an upper wall having the aperture therein, from which the peripheral skirt wall extends downwardly, and

wherein said upper wall and the upwardly convex part of the closure part are profiled such that the upwardly convex part bulges above the adjacent upper surface of the upper wall.

7. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 6 wherein said upper surface of the clamp part and the upwardly convex part of the closure part are profiled to form a smooth convex shape.

8. (Previously presented) A closure system according to claim 1 wherein the upper surface of the closure part adjacent to the said region is made of a thermoplastic elastomer material.

9. (Previously presented) A closure system according to claim 1

characterized in that the clamp part is made of a moldable plastics material and is engageable with the rim bounding the mouth opening of the vial.

10. (Potential amendment) A pharmaceutical vial having an upwardly facing mouth opening closed /by a closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial, and wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial via a snap-fit connection, wherein the snap-fit engagement parts are resiliently deformable so that they may deform to fit over the rim of the vial and then resiliently snap back to engage the vial via a snap-fit connection,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

11. (Potential amendment) A method of closing a vial having an upwardly-facing mouth opening bounded by a rim in the form of a flange having upper and lower surfaces extending transverse to its upper-lower axis, comprising

inserting into the mouth opening an elastomer closure part shaped to sealingly engage with the mouth opening, and having a lower surface to face the interior of the vial

and an opposite upper surface to face away from the vial, and capable of being punctured by a needle,

providing a clamp part able to engage with the flange around the rim of the mouth opening of the vial by a resilient snap-fit engagement of a snap fit part of the clamp part underneath a downwardly facing surface of such a flange part, wherein the snap-fit part is resiliently deformable so that it may deform to fit over the rim of the vial and then resiliently snap back to engage the flange of the vial via a snap-fit connection, and wherein the clamp part is able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having the snap-fit engagement parts thereon to engage the vial,

engaging the clamp part with the assembly of vial and closure part by said snap-fit engagement,

providing a cover part comprising an upper wall and a peripheral skirt wall, said cover part being engageable with the clamp part by means of a snap-fit between the clamp part and the skirt wall, wherein when so engaged said cover part covers the closure part and a lower surface of the cover part faces the upper surface of the closure part and engaging the cover part with the clamp part by said snap-fit.

12. (Previously presented – indicated to be allowed) A method of filling a pharmaceutical vial having an upwardly-facing mouth opening, comprising the steps of:

providing an assembly of an empty vial having an elastomer closure part shaped to sealingly engage with the mouth opening and having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle, and a clamp part engaged with the vial, and bearing upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial;

inserting a filling needle downwardly through the region of the upper wall of the closure part;

injecting a liquid medicament through the filling needle into the vial;  
withdrawing the needle to leave a residual puncture hole;  
engaging a cover part with the clamp part to cover the said region of the closure part by means of a snap-fit between a peripheral skirt wall of the cover part and the clamp part.

13. (Previously presented - indicated to be allowed) A method according to claim 12 further comprising, prior to engaging the said cover part, directing a source of heat at the residual puncture hole in the upper surface of the closure part to melt the elastomer material in the immediate locality of the puncture, and to thereby seal the residual puncture hole.

14. (Cancelled)

15. (Cancelled)

16. (Canceled).

17. (Previously presented) A pharmaceutical vial according to claim 10 retained in a stand, where said stand comprises:

a ring-shaped body having an inner perimeter adapted to engage with the base of the vial; and

an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein,

wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.

18. (Previously presented - indicated to be allowed) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening,



having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part,

further wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the sealing ridge being detachable from the clamp part.

19. (Previously presented - indicated to be allowed) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part,

further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

20. (Previously presented - indicated to be allowed) A pharmaceutical vial retained in a ring stand comprising:

A pharmaceutical vial having an upwardly facing mouth opening closed by a closure system, wherein the closure system comprises an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle; a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial; and a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture; wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part;

wherein the pharmaceutical vial is retained in a stand, where said stand comprises a ring-shaped body having an inner perimeter adapted to engage with the base of the vial and an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein, wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.

## Emmy Burns

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**From:** Kevin M. Hayes  
**Sent:** Monday, November 22, 2010 4:18 PM  
**To:** Smalley, James  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie  
**Attachments:** potential amendment (111510).doc

Dear Examiner Smalley:

Thank you for discussing the case again with us last week. We understand that the PTO would prefer that the proposed amendment more positively state that the snap fit parts do deform (instead of "may deform"). This would be fine with the Applicants and we attach a copy of the prior proposed amendment that has been marked up to show what we understated that the Office is requesting (see the red text).

Please let us know if this conforms to the Office's expectations.

Best regards, Kevin  
Kevin Hayes  
Klarquist Sparkman, LLP  
One World Trade Center  
121 S.W. Salmon Street, Suite 1600  
Portland, Oregon 97204  
Telephone: (503) 226-7391; (503) 595-5300  
Facsimile: (503) 228-9446; (503) 595-5301

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**From:** Smalley, James [mailto:James.Smalley@USPTO.GOV]  
**Sent:** Monday, November 15, 2010 12:55 PM  
**To:** Kevin M. Hayes  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Attorney Hayes,

I was on the phone with another attorney when you called, and we are having telephone difficulties making calls out of the USPTO today.

Would you be willing to claim this more positively, i.e. instead of "so that they may deform" you instead say "so that they deform"?

Please call to discuss. I am available now.

---

**From:** Kevin M. Hayes [mailto:kevin.hayes@klarquist.com]  
**Sent:** Thursday, November 11, 2010 6:05 PM  
**To:** Smalley, James  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley:

### **Listing of Claims for Discussion**

1. (Potential amendment) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial, and wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial via a snap-fit connection, wherein the snap-fit engagement parts are resiliently deformable so that they may deform to fit over the rim of the vial and then resiliently snap back to engage the vial via a snap-fit connection,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

2. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 1 wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the

sealing ridge being detachable from the clamp part.

3. (Cancelled)

4. (Previously presented) A closure system according to claim 1 wherein said frangible link is linked to the skirt wall of the cover part.

5. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 1 further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

6. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 5 wherein the clamp part comprises:

an upper wall having the aperture therein, from which the peripheral skirt wall extends downwardly, and

wherein said upper wall and the upwardly convex part of the closure part are profiled such that the upwardly convex part bulges above the adjacent upper surface of the upper wall.

7. (Previously presented – objected to, but indicated to be allowable) A closure system according to claim 6 wherein said upper surface of the clamp part and the upwardly convex part of the closure part are profiled to form a smooth convex shape.

8. (Previously presented) A closure system according to claim 1 wherein the upper surface of the closure part adjacent to the said region is made of a thermoplastic elastomer material.

9. (Previously presented) A closure system according to claim 1

characterized in that the clamp part is made of a moldable plastics material and is engageable with the rim bounding the mouth opening of the vial.

10. (Potential amendment) A pharmaceutical vial having an upwardly facing mouth opening closed /by a closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial, and wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial via a snap-fit connection, wherein the snap-fit engagement parts are resiliently deformable so that they may deform to fit over the rim of the vial and then resiliently snap back to engage the vial via a snap-fit connection,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part.

11. (Potential amendment) A method of closing a vial having an upwardly-facing mouth opening bounded by a rim in the form of a flange having upper and lower surfaces extending transverse to its upper-lower axis, comprising

inserting into the mouth opening an elastomer closure part shaped to sealingly engage with the mouth opening, and having a lower surface to face the interior of the vial

and an opposite upper surface to face away from the vial, and capable of being punctured by a needle,

providing a clamp part able to engage with the flange around the rim of the mouth opening of the vial by a resilient snap-fit engagement of a snap fit part of the clamp part underneath a downwardly facing surface of such a flange part, wherein the snap-fit part is resiliently deformable so that it may deform to fit over the rim of the vial and then resiliently snaps back to engage the flange of the vial via a snap-fit connection, and wherein the clamp part is able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having the snap-fit engagement parts thereon to engage the vial,

engaging the clamp part with the assembly of vial and closure part by said snap-fit engagement,

providing a cover part comprising an upper wall and a peripheral skirt wall, said cover part being engageable with the clamp part by means of a snap-fit between the clamp part and the skirt wall, wherein when so engaged said cover part covers the closure part and a lower surface of the cover part faces the upper surface of the closure part and engaging the cover part with the clamp part by said snap-fit.

12. (Previously presented – indicated to be allowed) A method of filling a pharmaceutical vial having an upwardly-facing mouth opening, comprising the steps of:

providing an assembly of an empty vial having an elastomer closure part shaped to sealingly engage with the mouth opening and having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle, and a clamp part engaged with the vial, and bearing upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial wherein the clamp part further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial;

inserting a filling needle downwardly through the region of the upper wall of the closure part;



injecting a liquid medicament through the filling needle into the vial;  
withdrawing the needle to leave a residual puncture hole;  
engaging a cover part with the clamp part to cover the said region of the closure part by means of a snap-fit between a peripheral skirt wall of the cover part and the clamp part.

13. (Previously presented - indicated to be allowed) A method according to claim 12 further comprising, prior to engaging the said cover part, directing a source of heat at the residual puncture hole in the upper surface of the closure part to melt the elastomer material in the immediate locality of the puncture, and to thereby seal the residual puncture hole.

14. (Cancelled)

15. (Cancelled)

16. (Canceled).

17. (Previously presented) A pharmaceutical vial according to claim 10 retained in a stand, where said stand comprises:

a ring-shaped body having an inner perimeter adapted to engage with the base of the vial; and

an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein,

wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.

18. (Previously presented - indicated to be allowed) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening,

having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part,

further wherein a lower surface of the segment of the cover part facing the upper surface of the closure part when engaged with the clamp part has a sealing ridge projecting therefrom to a sealing edge that follows a closed perimeter, so that when the cover part is engaged with the clamp part the sealing edge engages with the closure part to form an enclosure with the closure part, the segment which includes the sealing ridge being detachable from the clamp part.

19. (Previously presented - indicated to be allowed) A closure system for a vial having an upwardly-facing mouth opening bounded by a rim, the closure system comprising:

an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle,

a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial,

a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture,

wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part,

further comprising a downwardly extending plug part which can fit into the mouth opening of the vial, and an outwardly extending peripheral flange part, a downward facing surface of which can engage with the upward facing surface of a rim of the vial mouth opening in the form of a flange, and wherein upwardly of the flange part the closure part is upwardly convex.

20. (Previously presented - indicated to be allowed) A pharmaceutical vial retained in a ring stand comprising:

A pharmaceutical vial having an upwardly facing mouth opening closed by a closure system, wherein the closure system comprises an elastomer closure part shaped to sealingly engage with the mouth opening, having a lower surface facing the interior of the vial and an opposite upper surface facing away from the vial, and capable of being punctured by a needle; a clamp part able to engage with the vial, and able to bear upon the upper surface of the closure part to hold the closure part in a closing relationship with the mouth opening, the clamp part having an aperture therein through which a region of the upper surface of the closure part is exposed when the clamp part is engaged with the vial; and a cover part, engageable with the clamp part to cover the said region of the closure part, the cover part at least partly closing the aperture; wherein the cover part comprises an upper wall having a segment linked to the remainder of the cover part by a frangible link, said link severable to allow the segment to be sufficiently detached from the remainder of the cover part to thereby allow access to the region of the closure exposed through the aperture and further wherein the cover part comprises a peripheral skirt wall, and the skirt wall has a snap-fit engagement part adjacent its lower extremity to engage with the clamp part;

wherein the pharmaceutical vial is retained in a stand, where said stand comprises a ring-shaped body having an inner perimeter adapted to engage with the base of the vial and an outer perimeter extending radially beyond the outer diameter of the vial body in a direction perpendicular to the mouth-base axis direction of the vial retained therein, wherein the outer perimeter of the stand extends to substantially the same radial distance as the radially outermost extent of the clamp part when engaged with the vial.



**Emmy Burns**

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**From:** Kevin M. Hayes  
**Sent:** Tuesday, December 07, 2010 12:17 PM  
**To:** Smalley, James  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley:

Thank you for your email. We are happy that the Patent Office will allow the most recent proposed claims. You have our authority to charge any extension fees that may be required in connection with the Examiner's Amendment to Deposit Account No. 02-4550. Since the deadline is coming up on the 9<sup>th</sup>, we would be most appreciative if you could confirm entry of the Amendment before then. In the meantime, we will also file an interview summary.

Best regards, Kevin  
Kevin Hayes  
Klarquist Sparkman, LLP  
One World Trade Center  
121 S.W. Salmon Street, Suite 1600  
Portland, Oregon 97204  
Telephone: (503) 226-7391; (503) 595-5300  
Facsimile: (503) 228-9446; (503) 595-5301

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**From:** Smalley, James [mailto:James.Smalley@USPTO.GOV]  
**Sent:** Saturday, December 04, 2010 1:56 PM  
**To:** Kevin M. Hayes  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie  
**Importance:** High

Attorney Hayes,

We agree to enter the most recent proposed amendment by Examiner's Amendment. However, there appears to be a fee due, since the reply after final was not filed within 2 months of the mailing date of the Final Rejection.

I believe you would have to pay a three-month extension of time (to cover up to Dec. 09, 2010) but I do not handle fees, and I may be wrong. You may want to double check this.

Let me know if that is correct, and I will enter the requisite info. There is a form paragraph on the Examiner's Amendment which requires customer number, and your authorization to charge additional fees.

I am actually working all weekend, so if you receive this Saturday or Sunday, and can confirm the fees, I can type it up ASAP.

Best,

**James Smalley**  
Mechanical Patent Examiner  
United States Patent and Trademark Office  
Art Unit 3781  
400 Dulany St.  
Alexandria, VA 22314  
Phone: (571) 272-4547  
Personal Fax: (571) 273-4547  
USPTO Fax: (571) 273-8300  
Email: james.smalley@uspto.gov

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**From:** Kevin M. Hayes [mailto:kevin.hayes@klarquist.com]  
**Sent:** Thursday, December 02, 2010 7:54 PM  
**To:** Smalley, James  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley: Thank you for the update. We look forward to hearing from you, hopefully tomorrow. Best regards, Kevin

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**From:** Smalley, James [mailto:James.Smalley@USPTO.GOV]  
**Sent:** Monday, November 29, 2010 2:34 PM  
**To:** Kevin M. Hayes  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Attorney Hayes,

I can show this to my supervisor this week. It appears you have until Dec. 9th to reply, so time does not appear to be an issue, at least in the short term. He will let me know if it is to be entered by Examiner's Amendment or RCE.

Thank you.

**James Smalley**  
Mechanical Patent Examiner  
United States Patent and Trademark Office  
Art Unit 3781  
400 Dulany St.  
Alexandria, VA 22314  
Phone: (571) 272-4547  
Personal Fax: (571) 273-4547  
USPTO Fax: (571) 273-8300  
Email: james.smalley@uspto.gov

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**From:** Kevin M. Hayes [mailto:kevin.hayes@klarquist.com]  
**Sent:** Monday, November 22, 2010 7:18 PM  
**To:** Smalley, James  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley:

Thank you for discussing the case again with us last week. We understand that the PTO would prefer that the proposed amendment more positively state that the snap fit parts do deform (instead of "may deform"). This would be fine with the Applicants and we attach a copy of the prior proposed amendment that has been marked up to show what we understated that the Office is requesting (see the red text).

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Portland, Oregon 97204  
Telephone: (503) 226-7391; (503) 595-5300  
Facsimile: (503) 228-9446; (503) 595-5301

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**From:** Smalley, James [mailto:James.Smalley@USPTO.GOV]  
**Sent:** Monday, November 15, 2010 12:55 PM  
**To:** Kevin M. Hayes  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Attorney Hayes,

I was on the phone with another attorney when you called, and we are having telephone difficulties making calls out of the USPTO today.

Would you be willing to claim this more positively, i.e. instead of "so that they may deform" you instead say "so that they deform"?

Please call to discuss. I am available now.

---

**From:** Kevin M. Hayes [mailto:kevin.hayes@klarquist.com]  
**Sent:** Thursday, November 11, 2010 6:05 PM  
**To:** Smalley, James  
**Cc:** Emmy Burns  
**Subject:** RE: App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley:

Thank you for calling us on November 2, 2010. We understand from our discussion that the PTO has some concerns with regard to whether the previously discussed addition of the "snap fit connection" language includes sufficient structure. As we discussed on the 2<sup>nd</sup>, we understand that the PTO would agree that sufficient structure would be provided and the case should be allowed if Applicants amended the claims to include a further structural description of the snap fit connection. In that regard, we discussed an indication that the parts were resiliently deformable so that they could deform over the vial rim and snap back into place. We've attached a potential amendment making these changes. Please let us know if this would be acceptable. (You will see that we also propose to make a clarifying amendment in claim 11 to match the singular v. plural nature of the claim language.)

Best regards, Kevin  
Kevin Hayes

✓ Klarquist Sparkman, LLP  
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121 S.W. Salmon Street, Suite 1600  
Portland, Oregon 97204  
Telephone: (503) 226-7391; (503) 595-5300  
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**From:** Kevin M. Hayes  
**Sent:** Monday, October 18, 2010 10:10 AM  
**To:** 'james.smalley@uspto.gov'  
**Cc:** Emmy Burns  
**Subject:** App. No. 10/524,886 by Thilly & Vandecasserie

Dear Examiner Smalley:

Thank you for agreeing to discuss this case with us today at 3 p.m. ET (12 PT). Attached is a potential mark-up of the claims for discussion, which includes a potential amendment that was suggested in your Office action of June 9, 2010, on page 2.

Best regards, Kevin  
Kevin Hayes  
Klarquist Sparkman, LLP  
One World Trade Center  
121 S.W. Salmon Street, Suite 1600  
Portland, Oregon 97204  
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